

FYI-1003-01470

degussa.

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Shaun.Clancy@degussa.com
www.degussa.com

October 6, 2003



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Document Processing Center
EPA East (Mail Code 7407M)
Attn: TSCA Section 8(e)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20460-0001

Contain NO CBI



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Dear Madam or Sir:

Enclosed are summaries of 43 toxicology studies conducted by or for Degussa AG in Germany. These summaries reflect the results of one or more studies conducted on each of 21 chemical substances. Twelve of the summaries include information which we are reporting pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA). The remaining nine studies include information that suggests that the test substance may cause adverse health or environmental effects at high exposure levels. However, because these substances are manufactured or imported in the United States only in limited quantities for use as intermediates in chemical synthesis, they do not currently present a substantial risk to health or the environment. We are therefore submitting them to EPA on a "For Your Information" basis.

These 21 summaries are being submitted pursuant to a data review that Degussa is conducting in connection with its implementation of a new computer system that will permit Degussa Corporation in the United States to access data previously available only to Degussa AG in Germany. Recognizing that a large number of these studies might need to be reported under TSCA 8(e), Degussa proactively contacted EPA in mid 2002 and proposed to review the studies in batches and submit any 8(e) reportable data to EPA within 15 business days (now 30 calendar days) of completing its review of each batch. Degussa estimated that the review would take approximately six month to complete. In a memorandum received in November 2002, the Agency concurred in this approach.

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These studies were made available to Degussa Corporation in April 2003. Degussa's toxicologists in Germany have reviewed more than 750 studies on approximately 100 chemical substances and prepared English summaries of the results of 70 studies for evaluation by scientists in the United States for reporting under TSCA Section 8(e). This submission represents Degussa's review of this first batch of studies by our scientists in Germany and the United States, which was completed on September 12, 2003. Degussa has determined that approximately 1500 studies remain to be reviewed. As we have separately informed Ms. Ann Pontius of the Toxics and Pesticides Enforcement Division, we estimate that the review of the remaining studies will take an additional nine months to complete. We will continue to submit reportable and FYI studies to EPA as our review of subsequent batches is completed.

We appreciate your attention to this matter and request your comments regarding the approach we have taken. Please do not hesitate to call me at (973) 541-8047 if you have any questions or wish to discuss this matter further.

Best regards,



Shaun F. Clancy, Ph.D.

Memo

To: File

From: Shaun Clancy

CC:

Date: 10/06/03

Re: TSCA 8(e) Review – 32210-23-4

Two endpoints were provided by Fine Chemicals for 32210-23-4 p-tert-Butylcyclohexylacetate

- Acute Fish Tox (Carp)
- Algal Growth Inhibition

This chemical is used as an intermediate in organic synthesis and, when used in this way, is not expected to be used in a way such that human exposure outside of an industrial setting will occur or that an environmental exposure will readily result. The chemical may be used in products as a component of a perfume. Given the use levels of perfumes in these products, the concentration of any single component of a perfume, and the concentration of a component in wastewater, it is unlikely that there will be a significant human or environmental exposure. Appropriate Personal Protective Equipment is specified in the MSDS as are warnings not to allow the substance to be released. When used correctly the risk for human and environmental exposure is minimal.

The results of the acute fish tox and the algal growth inhibition studies indicate a level of toxicity that is considered to be moderate. Given the use pattern of the substance the results are probably not reportable under TSCA 8(e). The results will be submitted on an FYI basis.

Contains No CBI

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Fax

To: Shaun Clancy
S-SR-US-EHS

Fax-No. Recipient: 001-973 541 8040

Pages (total): 6

cc: Dr. W. Mayr/FC-TME-CSM

Initial notice of Information for possible TSCA 8e submission
p-tert-Butylcyclohexylacetate, CAS No. 32210-23-4

Dear Shaun,

please find attached data obtained for the above mentioned substance for assessment of possible TSCA reportability depending on the exposure situation.

June 23, 2003

I am at your disposal for any further questions.

I attach a short summary of the data together with the English summary of the reports.

Best regards

Sylvia Jacobi

Sylvia Jacobi

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Fine chemicals
Chemicals Safety
Management

FC-TME-CSM/Dr.Jbi/sch

Degussa AG • Head Office: Düsseldorf • Chairman of Supervisory Board: Karl Starzacher
Board of Management: Professor Dr. Utz-Helmut Felcht (Chairman of the Board of Management),
Dr. Alfred Oberholz, Dr. Thomas Schooneberg, Heinz-Joachim Wagner • District Court Düsseldorf,
Commercial Register No. 39635 • Commerzbank AG, Düsseldorf, Account 1353010, SWIFT COBADEDD
Degussa Bank GmbH, Frankfurt a. M., Account 300000, SWIFT DEGLDEFF • Deutsche Bank AG, Düsseldorf,
Account 3941820, SWIFT DEUTDEDD • Dresdner Bank AG, Düsseldorf, Account 2121220, SWIFT DRESDEFF 300

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Initial Notice of Information to be assessed for Possible TSCA,
Sec. 8e Reporting

Name / Trade name of the Substance	p-tert-Butylcyclohexylacetate
CAS-No.:	32210-23-4

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63457 Hanau-Wolfgang
Germany

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Fine chemicals
Chemicals Safety
Management
June 23, 2003

Human Health Effects

Environmental Effects

Degussa-Study-No.:	97-0304-DGO 97-0308-DGO
Other Source of information:	

Summary of Adverse Effects:

Source, Degussa AG internal report No. 96-0304-DGO

Guideline: EC Dir. 92/69 C1/EEC, GLP

Acute toxicity to fish (*Cyprinus carpio*)

LC₅₀: 8.6 mg/l, 96 h

Source, Degussa AG internal report No. 97-0308-DGO

Guideline: EC Dir. 92/69/EEC, 1992, GLP

Algae growth inhibition test with *scenedesmus subspicatus*.

Cell growth (biomass)

E_rC₅₀: 72 mg/l, 72 h

E_rC₁₀: 8.2 mg/l, 72 h

Growth rate:

E_rC₅₀: 22 mg/l

E_rC₁₀: 11 mg/l

NOEC: 6.8 mg/l (based on cell growth)

The ecotoxicological data suggest that the test substance is of moderate concern to the aquatic environment.

Nature and Extent of Risk Involved:

Depending on the exposure situation.

Information by	Date:
Dr. Sylvia Jacobi FC-TME-CSM	June 23, 2003

Hüls Aktiengesellschaft
DUV-Ps / BT
Prüfinstitut für Biologie
Bau 9015
Postfach 13 20
D-45764 Marl
Tel.: 0 23 65/49-26 63
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Eb

A b s c h l u ß b e r i c h t

FK 1380

Phase 2

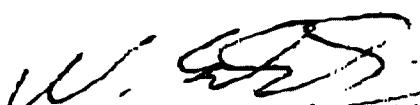
Bestimmung der akuten Wirkungen von **BUTYLCYCLOHEXYLACETAT, P-TERT.-**

gegenüber Fischen
(nach EG 92/69 C 1)

Auftraggeber:
Dr. Jegelka
GFB ZP
Hüls AG
45764 Marl

Der Unterzeichner erklärt, daß die im folgenden Bericht beschriebenen Versuche unter seiner Verantwortung nach den Grundsätzen der Guten Laborpraxis (GLP) entsprechend dem zur Zeit der Prüfung gültigen Chemikaliengesetz durchgeführt wurden und die Ergebnisse den Verlauf der Prüfung vollständig wiedergeben.

Marl, 10. 3. 97


.....
Dr. N. Scholz (Prüfleiter)

Der Abschlußbericht umfaßt 16 Seiten.

FK 1380.cb

Wp → 721S. → 7244. → 701
M2

97 - 0304 - 060

Abschlußbericht für Fischtest akut, Kurzzeittest nach EG 92/69 C1	FK 1380
	Seite 5 von 16

Summary

Test substance : BUTYLCYCLOHEXYLACETAT, P-TERT.-
 Test organism : Cyprinus carpio
 Test type : Acute toxicity 96 h LC₅₀
 Test conditions : Semi-static test
 according to 92/69/EEC; part C 1

Results

$$96 \text{ h } LC_{50} = 8.6 \text{ mg/l}$$

$$95 \% \text{ confidence limit} \\ 7.7 \text{ mg/l} - 9.6 \text{ mg/l}$$

After exposure for 96 h, the highest concentration at which no mortality ($\leq 10 \%$) occurred was,

$$96 \text{ h } LC_0 = 6.7 \text{ mg/l.}$$

After exposure for 96 h, the lowest concentration at which 100 % mortality occurred was,

$$96 \text{ h } LC_{100} = 12 \text{ mg/l.}$$

All concentrations are based on the substance.

Kopie
entspricht
Original Fl

Hüls Aktiengesellschaft
DUV - Ps / BT
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Postfach 13 20
D-45764 Marl
Tel.: 0 23 65/49-2662
Fax : 0 23 65/49-6050

A b s c h l u ß b e r i c h t

AW - 452

Phase 2

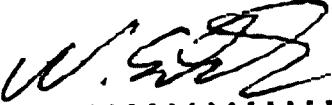
Bestimmung der Auswirkungen von
p-tert.-BUTYLCYCLOHEXYLACETAT

auf das Wachstum von *Scenedesmus subspicatus* 86.81. SAG
(Algenwachstumshemmtest nach Richtlinie 92/69/EWG)

Auftraggeber: Dr. Jegelka
GFB ZP P13
Hüls AG
45764 Marl

Der Unterzeichner erklärt, daß die im folgenden Bericht beschriebenen Versuche unter seiner Verantwortung nach den Grundsätzen der Guten Labor Praxis (GLP) entsprechend dem zur Zeit der Prüfung gültigen Chemikaliengesetz durchgeführt wurden und die Ergebnisse den Verlauf der Prüfung vollständig wiedergeben.

Marl, den 7.2.97


Dr. N. Scholz (Prüfleiter)

Der Abschlußbericht umfaßt 21 Seiten.
AWA452.F1

WP → 7215. → 7244. → Dok
15
M

97 - 0308 - D60

Summary

Test substance : p-tert.-BUTYLCYCLOHEXYLACETAT
 Test organism : Scenedesmus subspicatus
 Test type : Algal growth inhibition test
 according to 92/69/EEC

Results

On the basis of cell growth, a mean effective concentration can be calculated to

$_{72 \text{ h}} E_b C_{50}$: 17 mg/l,

$_{72 \text{ h}} E_b C_{10}$: 8.2 mg/l.

On the basis of the growth rate, a mean effective concentration can be calculated to

$(0 - 72 \text{ h}) E_r C_{50}$: 22 mg/l,

$(0 - 72 \text{ h}) E_r C_{10}$: 11 mg/l.

The NOEC value is

NOEC : 6,8 mg/l
 (based on cell growth)

All concentrations are based on product.